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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,164	07/23/2003	Eddie Reed	27497/2002	8006

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PAULA EVANS/  
C/O SONNENSCHN NATH & ROSENTHAL LLP  
P.O. BOX 061080  
WACKER DRIVE STATION, SEARS TOWER  
CHICAGO, IL 60606-1080

EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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09/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/625,164		REED ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	JEFFREY G. HOEKSTRA		3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-32 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-32 and 34-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 06/13/2008, amended claim(s) 25 and 34, new claim(s) 39-41 is/are acknowledged. The current objections and rejections is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Drawings***

2. The drawings were received on 06/13/2008. These drawings are *--not acceptable--*.
3. The Examiner notes the drawings received on 06/13/2008 appear similar to those received on 04/19/2006.
4. The drawings are objected to because they (a) appear to be informal photocopies of the invention which are not formal hand drawn illustrations of the claimed invention, (b) appear to be illegible and accompanied by dark and/or stray markings, and (c) they do not clearly illustrate at least the claimed limitations comprising *inter alia*: the collection element, the brush with bristles, and the inner tube, and/or the shield.
5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

6. Claim 25 is objected to because of the following informalities: the positive recitation in line 1 of "for detecting the presence" should apparently read "for detecting a presence". Appropriate correction is required.

### ***Double Patenting***

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Applicant is advised that should claims 39-41 be found allowable, claims 1 and 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 102***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 25-27 and 34-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Edens et al. (US 6,521,190 B1, hereinafter Edens).

11. Edens discloses a method for detecting human papilloma virus (HPV) in a collected vaginal specimen (column 1 line 5 - column 2 line 30, column 4 lines 28-51),

wherein the specimen contains cervical cells and few endocervical cells (column 1 line 5 - column 2 line 30), said method comprising:

- obtaining the specimen (abstract, column 3 lines 7-17) with a device (100,300) (as best seen in Figure 2) comprising a collection element (200) (as best seen in Figure 2) and a shield comprising an outer tube (110) surrounding the collection element (as best seen in Figures 1A and 2),
  - wherein the collection element comprises an inner tube (220) and a brush (210) attached to the inner tube (as best seen in Figure 2),
  - wherein the brush inherently has a brush longitudinal axis and comprises bristles (210) (column 3 lines 12-17) that are substantially perpendicular to the brush longitudinal axis (as best seen in Figure 2),
  - wherein the bristles comprise a flexible plastic material (column 4 lines 23-28) selected from a group consisting of: polyethylene, polyurethane, polyvinyl chloride, polysiloxanes, and nylon,
  - wherein the inner tube inherently has an inner tube longitudinal axis and the inner tube longitudinal axis runs parallel to the brush longitudinal axis (as best seen in Figure 2),
  - wherein the inner tube element and the outer tube element are cylindrical in shape (as best seen in Figure 2),
  - wherein an inner tube length and an outer tube length are roughly equal (as best seen in Figure 2), and

- wherein the device does not use an absorbent material to collect the sample (column 1 line 5 - column 2 line 30, column 4 lines 52-63); and
- detecting the presence of HPV, including high risk HPV, in the specimen through assaying (column 1 line 5 - column 2 line 30, column 3 lines column 4 lines 28-51).

***Claim Rejections - 35 USC § 103***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edens in view of Zavada et al (US 2003/0049828 A1, hereinafter Zavada). Edens teaches the claimed invention, as set forth above, except for expressly disclosing specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the specimen. Zavada teaches specimen testing including (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the specimen. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded

predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Edens and Zavada. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Edens with the components as taught by Zavada to achieve the predictable results of detecting HPV with the use of a collection element and various detection methods.

### ***Response to Arguments***

14. Applicant's arguments filed 06/13/2008 with respect to the rejection of claims 25-32 and 34-41 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of the claims under Edens, arguing Edens fails to disclose, teach, and/or fairly suggest the claimed method. Specifically Applicant argues:

- (a) "The brush must be a separate device";
- (b) "the brush used for sample collection be attached to the *retractable* inner tube of the device. This unitary structure has the net effect that the entire device is used during sample collection"; and
- (c) " This distinction in the structural design of the device encompassed by the instant claims has the added advantage of allowing *self collection*".

15. The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:



16. In response to applicant's arguments (a) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the brush must be a separate device") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

17. In response to applicant's arguments (b) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the brush used for sample collection be attached to the *retractable* inner tube of the device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

18. In response to applicant's arguments (b) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the entire device is used during sample collection) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

19. In response to applicant's arguments (c) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the device allows "self collection") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification

are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

20. Assuming *arguendo* Applicant intended to argue Edens fails to disclose, teach, and/or fairly suggest “said collection element comprising a brush... and an inner tube” “wherein said brush is attached to said inner tube”. The Examiner reiterates, as broadly as claimed and as cited above, Edens clearly shows in at least Figure 2 a device (100,300) comprising a collection element (200) comprising a collection a brush (210) attached to an inner tube (220).

### ***Conclusion***

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736